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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/13/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/670,756

Applicant(s)

RHODES ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 8, 10 and 55-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 8, 10 and 55-62 is/are rejected.
- 7) ☐ Claim(s) 63-65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
- _____, if the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 132(a)).
- See the attached detailed Office action for a statement of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-943)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence Comparison A

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV, claims 8, 10 and 55-65 in Paper No. 13, 9/30/2002 is acknowledged. The traversal is on the ground(s) that a search of Groups I, IV and VI can be made without burden. This is not found persuasive because a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter.

The requirement is still deemed proper and is therefore made FINAL. Claims 8, 10, 55-65 are pending and under consideration.

Claim Objections

Claims 8, 10 and 55-65 are objected to because of the following informalities: They contain limitations drawn to non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the

claims 8, 10 and 55-65 are rejected under 35 U.S.C. 112 first paragraph. Because the specification, while being enabling for an amino acid of SEQ ID NO: 20, does not reasonably provide enablement for an amino acid sequence which is 60%, 90%, 95% identical to SEQ ID

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NO: 20, or an amino acid sequence which comprises at least 15 contiguous amino acids of SEQ ID NO: 20. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 8, 10 and 55-62 are overly broad since insufficient guidance is provided as to which of the myriad of variant nucleic acids encode polypeptides which will retain the characteristics of PCIP9qm. Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the possible muteins of PCIP 9qm. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. For example, Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

Since the claims encompass variant nucleic acids and given the art recognized by the prior art, it would be obvious to one of ordinary skill in the art to attempt to make and use the claimed invention. See *In re* [unintelligible], 818 F.2d 1364, 53 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but

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whether, if experimentation is necessary, it is undue. The factors considered to be relevant in the instant case are set forth below:

(1) the breadth of the claims - The claims are drawn to an amino acid sequence which is 60%, 90%, 95% identical to SEQ ID NO: 20, or an amino acid sequence which comprises at least 15 contiguous amino acids of SEQ ID NO: 20.

(2) the nature of the invention - The instant invention is an amino acid sequence which is 60%, 90%, 95% identical to SEQ ID NO: 20, or an amino acid sequence which comprises at least 15 contiguous amino acids of SEQ ID NO: 20.

(3) the state of the prior art - The Voet reference demonstrates that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function.

(5) the level of predictability in the art - The Voet reference demonstrates the unpredictability of the protein art.

(6) the amount of direction provided by the inventor - Applicant has only taught the polypeptide of SEQ ID NO: 20.

(7) the existence of working examples - Working examples are provided for SEQ ID NO: 20.

(8) the quantity of experimentation needed to make or use the invention based on the predictability of the art as determined by the number of working examples, the nature of the prior art, the artisan, and the guidance provided in the instant specification and the prior art of record, it

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would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

Claims 8, 10 and 55-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

These are genus claims. The claims are drawn to an amino acid sequence which is 60%, 90%, 95% identical to SEQ ID NO: 20, or an amino acid sequence which comprises at least 15 contiguous amino acids of SEQ ID NO: 20. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the encoded SEQ ID NO: 20. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claim do not provide any structural attributes that would distinguish compounds in the genus from others in the protein class and missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because

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specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the polypeptide of SEQ ID NO: 20 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claims 55, 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Due to the limitation of "allelic variant" recited in the claim, a determination of what the claim as a whole covers indicates that elements which are not particularly described, e.g. the sequence of the claimed allelic variants, are encompassed by this claim. There is no actual reduction to practice of the claimed invention, or complete detailed description of the structure. A biomolecular sequence described only by a functional characteristic, in this case an allelic variant of a protein whose sequence is set forth in SEQ ID NO: 20, without any known or disclosed correlation between the function and the structure of the sequence is not a sufficient identifying characteristic. See *University of California v. Eli Lilly and Co.*, 43 USPQ2d at 1406. *University of California v. Eli Lilly and Co.*, 43 USPQ2d at 1406. The claim recites the function and the structure of the non-described allelic variants and the disclosed polypeptide with an amino acid sequence set forth in SEQ ID NO: 20. Weighing all factors in view of the level of knowledge and skill in the art,

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one skilled in the art would not recognize from the disclosure that the Applicant was in possession of the claimed invention.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55, 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 55, 59 are indefinite in the recitation of the term "naturally occurring". It is unclear whether this term imposes a required limitation on the claim, such that it only encompasses, for example, polypeptides amplified from human cDNA, or only sequences isolated from tissue which contains polynucleotides encoding the polypeptide. Therefore, the metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the applicant's filing date, or (2) a printed publication, or (3) a product or process, or (4) a sale, or (5) a use, or (6) a teaching, or (7) a combination of such things, in the United States or in any other country, before the applicant's filing date, or (8) the invention was anticipated by a person or persons, or (9) the invention was anticipated by a machine, or (10) the invention was anticipated by a process, or (11) the invention was anticipated by a composition of matter, or (12) the invention was anticipated by a method, or (13) the invention was anticipated by a device, or (14) the invention was anticipated by a material, or (15) the invention was anticipated by a substance, or (16) the invention was anticipated by a structure, or (17) the invention was anticipated by a system, or (18) the invention was anticipated by a method of manufacture, or (19) the invention was anticipated by a method of use, or (20) the invention was anticipated by a method of treatment, or (21) the invention was anticipated by a method of diagnosis, or (22) the invention was anticipated by a method of prevention, or (23) the invention was anticipated by a method of detection, or (24) the invention was anticipated by a method of identification, or (25) the invention was anticipated by a method of classification, or (26) the invention was anticipated by a method of analysis, or (27) the invention was anticipated by a method of synthesis, or (28) the invention was anticipated by a method of purification, or (29) the invention was anticipated by a method of separation, or (30) the invention was anticipated by a method of combination, or (31) the invention was anticipated by a method of modification, or (32) the invention was anticipated by a method of improvement, or (33) the invention was anticipated by a method of adaptation, or (34) the invention was anticipated by a method of application, or (35) the invention was anticipated by a method of implementation, or (36) the invention was anticipated by a method of operation, or (37) the invention was anticipated by a method of maintenance, or (38) the invention was anticipated by a method of repair, or (39) the invention was anticipated by a method of replacement, or (40) the invention was anticipated by a method of removal, or (41) the invention was anticipated by a method of destruction, or (42) the invention was anticipated by a method of disposal, or (43) the invention was anticipated by a method of recycling, or (44) the invention was anticipated by a method of reuse, or (45) the invention was anticipated by a method of repurposing, or (46) the invention was anticipated by a method of repackaging, or (47) the invention was anticipated by a method of relabeling, or (48) the invention was anticipated by a method of rebranding, or (49) the invention was anticipated by a method of reengineering, or (50) the invention was anticipated by a method of redesigning, or (51) the invention was anticipated by a method of restructuring, or (52) the invention was anticipated by a method of reorganizing, or (53) the invention was anticipated by a method of rearranging, or (54) the invention was anticipated by a method of reconfiguring, or (55) the invention was anticipated by a method of reformatting, or (56) the invention was anticipated by a method of reformatting, or (57) the invention was anticipated by a method of reformatting, or (58) the invention was anticipated by a method of reformatting, or (59) the invention was anticipated by a method of reformatting, or (60) the invention was anticipated by a method of reformatting.

Claims 56, 60 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No.

6117989 (Bandman et al.).

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The '989 patent discloses a calcium binding protein (column 3, lines 19-25). The calcium binding protein disclosed in the '989 patent is 62.3% identical to the amino acid sequence of SEQ ID NO: 20, thus claims 56 and 60 are anticipated.

Conclusion

Claims 63-65 are objected to.

Claims 8, 10, 55-62 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy
Patent Examiner
Art Unit 1646
December 12, 2002